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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

COYNESS L. ENNIX, JR., M.D.,

Plaintiff,

v.

ALTA BATES SUMMIT MEDICAL CENTER,

Defendant.

CASE NO. C 07-2486 WHA

DEFENDANT'S OBJECTIONS TO EVIDENCE SUBMITTED BY PLAINTIFF IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

DATE: April 24, 2008
TIME: 8:00 a.m.
DEPT: Ctrm. 9, 19th Flr
JUDGE: Hon. William H. Alsup

COMPLAINT FILED: May 9, 2007
TRIAL DATE: June 2, 2008

I. OBJECTIONS TO AN ENTIRE DECLARATION OR EVIDENTIARY TOPIC.

A. Objection To Paragraphs 2-9 And Exhibits B-F Of The Opposition Declaration Of Plaintiff's Counsel, Andrew Sweet.

Without any foundation regarding expertise in statistics, Mr. Sweet introduces sweeping statistical conclusions regarding the likelihood of African Americans being subjected to corrective action in the peer review process. Defendant objects to such evidence in its entirety under Federal Rules of Evidence ("FRE") 701, 702, 402 and 403. First, this objection will discuss Sweet's lack of qualifications to render such conclusions and thereafter it will address flaws in his methodology.

A trial court is required to distinguish between lay and expert testimony and then to determine whether the proffered testimony meets the applicable requirements of either FRE 701 or 702. *Jarden v. Amstutz,* 2006 US App. LEXIS 686 *18-21 (9th Cir. 2006); *United States v. Figueroa-Lopez,* 125 F.3d 1241, 1246 (9th Cir. 1997). Here, Sweet's declaration contains no foundation for his offering an opinion regarding statistics; therefore, the evidence must be treated as lay testimony. The declaration is however barred by the requirements of FRE 701, one of which is that the testimony cannot be based on scientific, technical or other specialized knowledge within the scope of FRE 702.

Assuming arguendo that Sweet's "opinion" should be analyzed under the Court's "FRE 702 gatekeeping power"[1], there are obvious flaws in methodology which preclude admission of such evidence which is a purported comparison of the racial composition of Medical Staff members in 2004-2006 (Exh. A to the Sweet Declaration) with peer review actions undertaken by many different Medical Staff leaders during the time period of 1992 to 2007 (Exh. F to the 2/26/08 Hernaez Declaration; hereafter "Exhibit F"). They are:

[1] *See, Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 589-90 (1993) for a description of the Court's obligation to review scientific or technical evidence for relevancy and reliability.

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- The data for the racial composition of the Medical Staff is tentative, incomplete, and limited to two years (2004-2006) while the actions depicted in Exhibit F cover a 15 year period. As noted on Exhibit A (page 28 of 28)[2] to the Sweet Declaration, the Medical Staff does not keep race statistics so many of the notations were guesses and the data is substantially incomplete. Only 55% of the persons listed are identified by race. Such an incomplete pool cannot give rise to sound statistical conclusions. Given the different time periods covered, Exhibit A is not the overall pool for Exhibit F as illustrated by the fact that Physician H (Jaikrishna Balkissoon)[3] is not listed on Exhibit A.

- The number of peer review actions undertaken at the MEC level (the same level at which Ennix's peer review was conducted) involves 16 different physicians over the time period from 1992 to 2007.[4] 16 is a very small number of actions to review, and Sweet is not qualified to attest as to whether this minimal number of actions occurring over an extended time period affects the validity of the conclusions Plaintiff argues from Sweet's analysis.[5] The size of the group is reduced even further if the examined peer review actions are limited to ones involving any of the decision makers responsible for Ennix's peer review.[6] Exhibit F shows the variety of physicians involved in the various peer review decisions. Only two instances identify William Isenberg, M.D., the individual Ennix accuses of organizing the corrective action against him, as a primary decision-maker. Moreover, the sample size is even more reduced if the peer review actions experienced by African Americans are compared to those experienced by Caucasians as Sweet does in ¶¶ 8 and 9 on page 3 of his Declaration. There are only

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[2] The page references are to the e-filing pagination.

[3] Dr. Balkissoon has been publicly identified in State Medical Board records. See Exhibit 1 to Defendant's Request for Judicial Notice.

[4] One physician (G) is the subject of two separate peer review processes.

[5] Those conclusions, which must be entirely disregarded, are summarized in Plaintiff's Opposition Brief at page 3:9-11.

[6] When peer review is conducted at the MEC level, the decision-makers are generally the Medical Staff Officers who hold such offices for two year terms. See, Article IX of Exh. A to the Isenberg Declaration submitted in support of Defendant's Motion for Summary Judgment. Exhibit F shows no overlap in primary decision makers in 1992-1995 as compared with 2007.

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three individuals identified as African Americans on Exhibit F. No probative statistical conclusions can be drawn from such isolated actions towards such a small number of individuals which may well be why these theories are propounded by Plaintiff's lawyer rather than a statistician. *See, Morita v. Southern California Permanente Medical Group,* 541 F.2d 217, 220 (9th Cir. 1976), *cert. denied*, 429 U.S. 1050 (1977) (a showing that only one out of eight promotions was to a minority employee was insufficient to prevent to prevent a Rule 41 (b) dismissal of the case as ..."statistical evidence derived from an extremely small universe...has little predictive value and must be disregarded".)

- Sweet assumes that an individual who self-identifies as predominately "Indian, African American and Native American", and who appears to have an Indian surname, is African American (Sweet Declaration 2:26-27). There is no foundation for that assumption, and given the small number of peer review actions, the assumption is likely to have an impact upon conclusions (which Sweet is in no event qualified to analyze).

- Sweet does not provide a foundation for his division of issues into behavioral problems versus standard of care issues, and there is no logical basis for drawing such a distinction. Behavioral issues, such as not cooperating with other patient care providers, can have a significant impact on patient care. Moreover, some of the physicians listed on Exhibit F are described as having problems in both categories. See, for example, Physician A (inappropriate treatment of others and questionable prescription practices) and Physician B (late for procedures and diagnostic issues). Sweet's division of these characteristics cannot support a statistical conclusion. Moreover, the notion that somehow behavioral issues are less serious or result in less onerous corrective action is at odds with the underlying exhibit. See the description for Physician G (page 6 of Exhibit F) which notes that a Caucasian physician was subjected to a total suspension of privileges for 59 days and had ongoing restrictions thereafter for conduct characterized as violation of the Bylaws and Rules and Regulations.[7]

[7] Such corrective action directed towards a Caucasian doctor (with Dr. Isenberg being

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- Sweet's analysis, which is based on a comparison of numbers only, essentially argues that such numbers could not have occurred by chance. But these peer review actions did not occur by chance, rather they occurred because a variety of Medical Staff leaders had significant concerns impacting the quality of patient care delivered by members of the Medical Staff. *See, Coleman v. Quaker Oats Company,* 232 F.3d 1271, 1281-3 (9th Cir. 2000), *cert. denied,* 533 U.S. 950 (2001) (statistical evidence that employees over 40 were twice as likely to be laid off than were employees under 40 was insufficient to preclude the granting of summary judgment in an ADEA case because the statistics did not account for factors pertinent to the lay off decision, such as job positions held and qualifications). *See also,* the *Coleman* Court's citation to *Rea v. Martin Marietta Corp.,* 29 F.3d 1450, 1456 (10th Cir. 1994) as holding that ... "to raise an inference of discrimination, statistical evidence should account for possible nondiscriminatory variables". *Coleman v. Quaker Oats Co.,* at 1283. Sweet makes no showing of statistical significance.

- Because of the very small number of peer review actions summarized on Exhibit F, we have proof that the "statistical" conclusions advanced by Plaintiff are inconsistent with the actual facts of the peer review actions. Two of the individuals identified by Plaintiff as "physicians of color" (Physicians H and I on Exhibit F) had their licenses revoked by the California Medical Board (with the revocations stayed subject to probation and other conditions). (Exhibits 1 and 2 to Defendant's Request for Judicial Notice.) Surely, this evidence of the legitimate nature of the peer review actions negates entirely any attempt to use these two instances as proof of race discrimination.

B. Objection to the Declaration of Physician H (Jaikrishna Balkissoon, M.D.) In Its Entirety.

Defendant objects to Physician H's declaration on the grounds of FRE 402, 403, 701, 802 , F.R.Civ.P. 56(e) and Local Rule 7-5. Because the fundamental objection is relevancy and because the declaration is riddled with objectionable statements,

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one of the decision makers) is more severe than the corrective action received by Dr. Ennix.

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Defendant asks that the entire declaration be rejected. The declaration is replete with conclusions and arguments in violation of Local Rule 7-5. Examples of such objectionable content are: "From 1997 to 2003, I was subject to an extensive, harsh and procedurally irregular peer review process at Summit..." (1:25-26)[8]. "...I understand that many of the details of my peer review process are similar to those of Dr. Ennix's" (2:8-9). "Also, like Dr. Ennix, ABMSC targeted me for an extensive and protracted peer review process..." (2:12-13). "Additionally, ABSMC employed irregular procedures in my peer review" (2:15-16). "Like Dr. Ennix's case, ABSMC found an obscure outside peer reviewer who they paid to review cases of mine that they had selected, many of which had already been cleared of care issues through the normal review process" (2:16-18). "The intensive peer review concerned me not only because it was unwarranted..." (4:22-23). "Also during this time, the Hospital's Institutional Review Board closed down the clinical research studies I had brought to ABSMC, citing clerical errors—a criticism that appeared too minor to justify closing the studies" (4:25-5:2)[9]. "ABMSC was a hostile environment for me to work" (7:6-7). "ABMSC, however, has already breached this aspect of the confidentiality agreement" (8:1-2).

The Declaration is replete with inadmissible hearsay. (FRE 802). All references to Dr. Ennix's peer review (2:8-9, 2:13-20) are hearsay as such information must have been gained through discussions with Ennix or his counsel. Balkissoon did not participate in Ennix's peer review and had in fact resigned from the Summit Medical

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[8] Citations are to page and line numbers.

[9] Defendant produced to Plaintiff's counsel in discovery the letter from the Institutional Review Board ("IRB") dated 5/29/02 to Physician H describing the bases for its termination of the physician's research activities. Such letter is attached as Exhibit 1 to the Supplemental Declaration of Alex Hernaez submitted with Defendant's Reply ("Supplemental Hernaez Dec."). Characterizing the criticisms as "clerical errors" is not only an unsupported opinion, it is also a lie. The IRB, citing findings of an audit by the American College of Surgeons Oncology Group, rejected the physician's contention that the issues were flaws in his record-keeping process and instead described the audit's findings as serious in such areas as not obtaining patient consent forms before starting experimental treatment, not following IRB protocol, treatment doses being incorrectly administered, calculated and documented, and inconsistent data reporting for treatment administration. (Exhibit 1, p. D 5736).

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Staff before the Ennix peer review process commenced.[10] Other hearsay statements which should be excluded are: "After my first year of practice, Hill Physicians HMO, . . . told me to stop taking breast cancer cases. . . (3:18-20). "Hill Physicians told me if I continued to take such cases, the HMO would drop me" (3:20-21). "When I complained to Dr. Moorstein about this extensive review, he responded: 'What are you going to do about it?'" (5:23-24). "I learned from one of my former referring gynecologists that Dr. Steven Stanten informed him that I was no longer practicing due to 'trouble at the hospital'..." (8:1-4). "Additionally, I was informed that Dr. Lisa Bailey discussed my peer review with a medical staff officer at California Pacific Medical Center..." (8:4-6). Additionally, Defendant raises a relevancy objection to ¶ 8 (3:18-20). Physician H's relations with Hill Physicians HMO in about 1993 have no conceivable bearing on any issue in this case.

The Balkissoon declaration is entirely irrelevant for the purpose for which it is offered; namely, to suggest that Ennix's peer review occurred because of race discrimination. It is not possible to accept the argumentative thrust of the Balkissoon declaration, that he was subjected to race discrimination regarding his peer review process. As seen by Exhibit 2 to Defendant's Supplemental Request for Judicial Notice ("Request"), the Medical Board of California filed an Accusation (the Accusation is Exhibit (2)(A) to the Request) against Balkissoon in January 2005 seeking, inter alia, to revoke or suspend Balkissoon's license.

The Accusation charged, inter alia, relative to surgeries Balkissoon performed at Summit Medical Center from January 1998 through January 2002:

- Respondent demonstrated a severe lack of knowledge of the role of imaging studies in developing a treatment plan for a surgical patient" (Exh. (2)(A), 5:7-8).
- Respondent failed to review the CT scan taken on December 1, 1999 upon N.H.'s admission...". Because this information was not incorporated into the

[10] See Exh. F, page 7.

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patient's management plan, N.H. was taken to the operating room (OR) unnecessarily and the surgery addressed the incorrect problem." (Exhibit (2)(A), 7:22-25).

- "Respondent's failure to provide adequate coverage for his patients during K.L.'s second hospitalization reflects a serious indifference to toward the welfare of his patients." (Exhibit (2)(A), 10:17-18).

Balkissoon settled these charges by accepting a stayed license revocation, a three year probation and mandatory clinical education. As the State sets minimum standards for patient safety[11], the State's action toward Balkissoon arising out of the practice that was peer reviewed by the Summit Medical Staff must be seen as negating entirely Balkissoon's conclusory claim of race discrimination.[12]

Moreover, any arguable relevancy is substantially outweighed by FRE 403 factors. As seen by Exhibit F to the 2/26/08 Hernaez Declaration, the decision makers in Balkissoon's peer review differed substantially from those in Ennix's peer review. An examination of the Ennix peer review in the course of this litigation has generated many depositions, the production of thousands of pages of documents and several discovery disputes. An examination of Balkissoon's peer review process would require a substantial expenditure of time and lead to undue confusion.

C. Objections To The Entire Declarations Of Alex Zapolanski, M.D. And William S. Weintraub, M.D.

Defendant objects to the Zapolanski and Weintraub declarations on the grounds of lack of relevancy, undue confusion and undue consumption of time. FRE 401, FRE 403. This information was not presented to or available during the peer review process and hence can have no bearing on the decision-making in such process. It has

[11] See, *Bonner v. Sisters of Providence Corp.,* 194 Cal. App. 3d 437, 444-446 (1987) (Decision of the Medical Board not relevant to mandamus proceedings concerning a Hospital's revocation of certain staff privileges because the hospital had a higher standard of care.)

[12] Balkissoon did not exhaust administrative remedies concerning the actions of the ABSMC's Medical Staffs to terminate or otherwise restrict his privileges. Instead, he resigned from the Staffs. Exhibit (2)(A) to Defendant's Request, 3:9-16.

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no relevancy to whether the peer review process was racially discriminatory. Section 1981 does not provide a vehicle for a wholesale review of the peer review process, a review which this Court has already determined was waived by Plaintiff in his failure to exhaust available administrative remedies. *See,* 8/28/07 Order re Motion to Dismiss.

II. OBJECTIONS TO PARTICULAR STATEMENTS.

A. Objections to Dr. Ennix's Opposition Declaration.

¶ 5 (2:16-18) use of the term "cleared"; conclusion that the "established peer review process found no concerns regarding patient safety".	Conclusory, Argumentative. FRE 701, Local Rule 7-5 (b).
¶ 6 (2:23-24) as to "unvetted" and "bogus allegations".	Conclusory, Argumentative. FRE 701, Local Rule 7-5 (b).
¶ 8 (3:4-8) as to "cleared" and "debunking the bogus statistics".	Conclusory, Argumentative. FRE 701, Local Rule 7-5 (b).

B. Objection To Plaintiff's Misleading Use Of Deposition Citations To Support The Argument That Dr. Ennix's Peers Had Similar Complications And Worse Mortality Rates Than Did Ennix.[13]

Russell Stanten Dep. 65:8-22, 66:7-17; 71:14-72:4, 76:24-77:9, 79:13-18, 96:14-97:23.	These citations, many objected to on vague or compound grounds during the deposition, involved questions as to whether other cardiac surgeons ever had complications without any attempt to ask about circumstances similar to the results exhibited by Ennix in four minimally invasive valve procedures ("MIV") done between 1/28/04 and 2/5/04. Russell

[13] This argument, together with the citations, is set forth at page 19:10-27 of Plaintiff's Opposition Brief.

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	Stanten specifically negated use of this testimony for the proposition now advanced by Plaintiff; namely, that the "complications" were comparable. Dr. Stanten testified: Q.: "Have, to your knowledge, any of those cardiac surgeons ever had those cluster of cases reviewed outside of the cardiothoracic peer review committee?..." A.: I can't recall any other situations where there was a cluster of these severe technical complications over that short a period of time that required review by the cardiothoracic peer review committee or any other body." R. Stanten 97:2-12 (Exh. N to the Sweet Declaration). Dr. Stanten further testified that his answers regarding complications could not be compared to the unprecedented results of Ennix's MIV procedures: (118:7-119:12)[14]: Q (by McClain): "You spoke very generally in response to general questions about complications arising in a short period of time for other surgeons, do you recall that testimony?

[14] These excerpts are attached as Exhibit 2 to the Supplemental Hernaez Dec.

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	A: Yes. Q: Were the cases you were thinking of in any way comparable to the results of the four surgeries that Dr. Ennix did using the minimally invasive procedure in early 2004? [Objection by Emblidge] A: No. I believe there were substantial differences between what was referred to in the questioning and what occurred with Dr. Ennix. Q: Can you explain to us what you meant by severe complications to multiple patients?[15] A: In these cases, there were severe technical complications resulting in the need for reoperation in several of the patients, one of which was the valve was removed and replaced during the operation, one of which the valve was removed and replaced at a second operation, and the third of which the patient died before the valve could be removed and replaced but he clearly needed that."
Hon Lee Dep. 20:23-21:6, 32:7-23, 100:25-102:11.	Nothing in these excerpts suggests that Lee believes other doctors experienced the

[15] This is a reference to an earlier answer to a question from Plaintiff's counsel which appears at 94:8-16 (Exhibit 2 to the Supplemental Hernaez Dec.).

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	full range of complications in as short a period of time as did Ennix with the MIV procedures. Asking someone whether other cardiothoracic surgeons have had patients who have died during or shortly after surgery (Lee Dep. 101:7-14) hardly leads to the conclusion that other doctors experienced equivalent complications.
Leigh Iverson Dep. 86:24-87:9 cited for the proposition that Iverson and Khan had similar complications in an earlier MIV procedure. Plaintiff's Opp. Brief, 11:20-25.	Incomplete, Misleading reading of the testimony. First, Iverson testified that he was not sure such procedure qualified as a minimally invasive procedure. Iverson Tr. 85:8-20 (Exh. K to the Sweet Declaration). And, nowhere does Iverson say that he experienced the lengthy time, excessive blood product use, return to surgery and death experienced in Ennix's first four procedures. (Isenberg Declaration 6:12-15); (R. Stanten Dep. 118:7-119:5.)

C. Objections To Plaintiff's Misleading Use Of The March 2007 California Report On Coronary Artery Bypass Surgery For The Proposition That Ennix's Mortality Rate Was Equivalent To That Of His Peers, And Objections To Statistically-Related Deposition Cites.

Sweet's Declaration, ¶ 29, 5:26-6:11.	Lack of Foundation, Improper Opinion, Argumentative. FRE 602, 701, 702. Sweet's global statement that the California report shows that Ennix's mortality rate "was within the acceptable

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	range" falls to note that the mortality rates in the California study are for isolated coronary bypass procedures only ("CABG" or "ABG") in 2003-2004 and not for all cardiac procedures performed by Ennix. A review of the statistically-adjusted[16] mortality rates for valve procedures and coronary bypass procedures relied upon by the AHC covering the period of 1999-4/30/05 (Exhibit A to the Paxton Declaration filed on 2/26/08, pages 21 of 70 and 70 of 70) shows that the significantly higher mortality rates are in isolated valve procedures and combined AGB and valve procedures, leading to an overall mortality rate over the 6.5 year period of 7.4% as compared with his partners' overall rate of 3.8%. If one looks at coronary bypass procedures only on p. 70 of 70 attached to the Paxton Declaration, the results are not as disparate as when the

[16] See Paxton Dep. 118:1-17 attached as Exhibit 3 to the Supplemental Hernaez Dec. for a confirmation that the STS mortality data reviewed by the AHC was risk-adjusted by the Society for Thoracic Surgery.

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	valve procedures are added.[17] As Ennix was performing both valve and CABG procedures, it is misleading to look only at the CABG-related statistics of the California report.
Weintraub Declaration ¶ 5, 2:18-3:3	Relevancy and Undue Prejudice. FRE 402, 403. The California 2003-2004 CABG report does not cover all of the procedures performed by Ennix, excluding those where his mortality rate was substantially higher than his peers.
Cites used to support Plaintiff's argument that three cardiac surgeons called into question the statistics relied upon by the AHC. Paxton 145:1-9, Paxton, 159:5-10, Horn 216:2-9. See, Plaintiff's Opposition Brief, 13:12-14.	Misleading citation of evidence. All of these cites are from members of the AHC asking for their interpretation of what persons told them. None of them said that they concluded the cardiac surgeons were questioning the statistics. Paxton Dep. 145:10-15; 159:11-15. For example: The cited testimony (216:2-9; Exhibit V to the Sweet Declaration) from Dr. Horn is: Q: "And Dr. Kahn (sic) tells you he's hesitant to accept this if the risk is stratified. Do you see that? A. Right. Q. What does that mean? A. I don't remember.

[17] Significantly, the MIV procedures were all valve replacements—not CABG procedures.

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	Q. Was he expressing to you that maybe in his opinion the statistics were not significant? A. I don't remember. You would have to ask him."

D. Objections To Argumentative Statements In The Sweet Declaration.

Sweet Declaration ¶ 27, 5:19-22.	Lack of Foundation as to what the exhibits show. Argumentative. FRE 602; Local Rule 7-5 (b). While Sweet asserts that the documents show Ennix "visited" the patient, such assertion is not relevant. The issue was whether Dr. Ennix "examined" the patient even though he did not make a contemporaneous note and backdated the progress note he made a day later (Ennix Dep. 239:22-25; Exh. 5 to the Supplemental Hernaez Declaration; Exh. 7 to Hernaez's Supplemental Dec.)

DATED: April 3, 2008

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